

A community-based motivational personalised lifestyle intervention to reduce BMI in obese adolescents: results from the Healthy Eating and Lifestyle Programme (HELP) randomised controlled trial

Deborah Christie,¹ Lee Duncan Hudson,² Sanjay Kinra,³ Ian Chi Kei Wong,⁴ Irwin Nazareth,⁵ Tim J Cole,⁶ Ulla Sovio,⁷ John Gregson,⁸ Anthony S Kessel,⁸ Anne Mathiot,^{6,9} Stephen Morris,⁹ Monica Panca,⁹ Silvia Costa,⁹ Rebecca Holt,⁹ Russell M Viner⁶

For numbered affiliations see end of article.

Correspondence to

Dr Deborah Christie, Child and Adolescent Psychological Services, 250 Euston Rd, London NW1 2PQ, UK; deborah. christie@uclh.nhs.uk

Received 10 October 2016 Revised 31 March 2017 Accepted 4 April 2017 Published Online First 7 July 2017



► http://dx.doi.org/10.1136/ archdischild-2017-312807



To cite: Christie D, Hudson LD, Kinra S, *et al. Arch Dis Child* 2017;**102**:695–701.

ABSTRACT

Objective Approximately 7% of children and young people aged 5–15 years in the UK have obesity at a level likely to be associated with comorbidities. The majority of multicomponent lifestyle programmes have limited applicability and generalisability for British adolescents. The Healthy Eating and Lifestyle Programme (HELP) was a specific adolescent-focused intervention, designed for obese 12 to 18-year-olds seeking help to manage their weight. Participants were randomised to the 12-session HELP intervention or standard care. The primary outcome was difference in mean body mass index (BMI) (kg/m²) between groups at week 26 adjusted for baseline BMI, age and sex.

Subjects 174 subjects were randomised (87 in each arm), of whom 145 (83%) provided primary outcome data at week 26.

Results At week 26 there were no significant effects of the intervention on BMI (mean change in BMI 0.18 kg/m^2 for the intervention arm, 0.25 kg/m^2 for the control arm; adjusted difference between groups: -0.11 kg/m^2 (95% CI -0.62 to 0.40), p=0.7). At weeks 26 and 52 there were no significant differences between groups in any secondary outcomes.

Conclusion At minimum this study reinforces the need for higher level, structured interventions to tackle the growing public health burden of obesity in the UK and internationally. The HELP intervention was no more effective than a single educational session for reducing BMI in a community sample of obese adolescents. Further work is needed to understand how weight management programmes can be delivered effectively to young people from diverse and deprived backgrounds in which childhood obesity is common. The study has significant implications in terms of informing public health interventions to tackle childhood obesity. **Trial registration number** ISRCTN: ISRCTN99840111.

BACKGROUND

Approximately 7% of children and young people in the UK have obesity at a level likely to be associated with comorbidities.¹ Over 1% of adolescents have extreme obesity, with a body mass index

What is already known on this topic?

- Approximately 7% of children and young people in the UK have obesity at a level likely to be associated with comorbidities.¹
- The majority of multicomponent lifestyle programmes have limited applicability and generalisability for British adolescents.

What this study adds?

- The evidence-based Healthy Eating and Lifestyle intervention was no more effective than a single educational session for reducing body mass index in obese adolescents.
- Further work is needed to understand how weight management programmes can be delivered effectively to young people from diverse and deprived backgrounds in which childhood obesity is common.
- This study reinforces the need for higher level, structured interventions to tackle the growing public health burden of obesity in the UK and internationally.

(BMI) more than 3 SD above the mean.² Multicomponent lifestyle modification programmes recommended by the National Institute for Health and Care Excellence³ are aimed at primary school children, inappropriate for adolescents developing diet and activity patterns that will stay with them into adult life. Body image and self-esteem issues become important, and behaviour change increasingly depends on individual motivation. Adolescent studies in non-UK academic/tertiary care centres with highly specialised staff involving white, middle-class, motivated families^{4 5} have limited applicability and generalisability for British adolescents. Reviews conclude a need for adequately powered high-quality trials in representative



Original article

populations with integral process evaluation and appropriate lifestyle tools. $^{4\,5}$

The Healthy Eating and Lifestyle Programme (HELP) is an evidence-based multicomponent intervention focusing on enhancing motivation to change, developing self-efficacy and self-esteem for obese 12 to 18-year-olds seeking help to manage their weight. Unpublished pilot data in a clinical setting for 20 subjects aged 13–17 years showed a mean BMI reduction of 1.7 kg/m^2 over 6 months, equivalent to a 0.4 SD effect size. We report a randomised controlled trial of HELP in a community sample of obese adolescents. Our primary aim was to assess whether HELP delivered by graduate mental health workers in the community was more effective in reducing BMI in obese adolescents than enhanced standard care. Secondary aims were to assess cost-effectiveness and impact on cardiometabolic risk and psychological function.

METHODS

Design

We undertook a randomised efficacy trial consistent with a phase III trial in the Medical Research Council (MRC) guidance on complex interventions.⁶ Subjects were randomised to receive either HELP or enhanced care for 6 months. Details are available in the published protocol.⁷

Intervention

HELP is a 12-session family-based weight-management programme for adolescents. Motivational interviewing⁸ and solution-focused approaches⁹ were used to increase engagement and concordance. The programme was delivered in local community settings by psychology graduates who completed a 5-day training programme on obesity and good clinical practice, with 2 of the 5 days focusing on behaviour change techniques

Session content included:

- 1. 'Where and how we eat'-modifying eating behaviours/ encouraging regular eating patterns;
- 2. 'What we do'—decreasing sedentary behaviour/increasing lifestyle and programme activity;
- 3. 'What we eat'—reducing intake of energy-dense foods/ increasing healthy nutritional choices;
- 4. 'Why we eat'-addressing emotional eating triggers.

Comparator

Enhanced standard care was a 40–60 min standardised educational session incorporating Department of Health guidance on eating behaviours, healthy eating and activity, delivered by a primary care nurse (or trained nurse practitioner) in the participant's general practice within 3 months of recruitment.

Sample and recruitment

Eligibility was initially defined as young people (13–17 years) with BMI >98th centile for age and sex according to the UK 1990 growth reference, recruited from primary care and community settings within the Greater London area. Exclusion criteria were:

- 1. Diagnosed significant mental health problems/undergoing mental health treatment.
- 2. Chronic illness (apart from asthma unless severe requiring excessive doses of regular steroids), known secondary obesity, monogenic obesity syndrome or use of medications known to promote obesity; and those with BMI ≥40 kg/m².
- 3. Significant learning disability or lack of command of English sufficient to render them unable to participate effectively in the intervention.

4. Participation in formal behavioural weight-management programmes in the past 12 months.

Due to slow recruitment, we widened the age range to 12-19 years and used a revised definition of obesity, that is, BMI >95th centile for age and sex and BMI <45 kg/m².

We recruited through:

- 1. general practitioner practices, via the local Primary Care Research Network, in areas with known high prevalence of obesity;
- 2. paediatricians, school nurses, pharmacists and dietitians;
- 3. advertising on social media, the study website, community media, newsletters, community youth groups, secondary schools and colleges.

Baseline assessments were undertaken at the National Institute for Health Research Great Ormond Street Hospital Clinical Research Facility (CRF). Participants were given a £20 iTunes or high street store voucher at entry and again at completion, and reimbursed for travel costs.

Randomisation

Participants were randomised 1:1 to the two arms and balanced for sex after baseline assessment independently of the investigators by the Health Services Research Unit University of Aberdeen.

Outcomes

Outcomes were measured at baseline, mid-treatment (week 13), end of intervention (week 26) and 6 months postintervention (week 52) (see table 1 for details on data collected at each time point). Outcomes were assessed by clinical assessment, venepuncture and psychological questionnaires. The primary outcome (BMI, calculated from measured height and weight) was assessed by trained CRF nurses blind to treatment status.

Primary outcome

Difference in mean BMI (kg/m^2) between groups at the end of the intervention (week 26), adjusted for baseline BMI, age and sex. Positive differences reflect an increase, negative a decrease throughout.

Secondary outcomes

- 1. Anthropometric measures:
 - i. BMI (week 52)
 - ii. BMI; SD score (zBMI) weeks 0, 26 and 52. Waist circumference; weeks 0, 26 and 52
 - iii. Non-invasive measurement of fat mass and fat mass percentage using Tanita 418 bioimpedance scales. Fat mass (kg) was calculated from the impedance value using the formula validated in obese adolescents,¹⁰ and fat mass percentage was calculated dividing fat mass by body mass.

Week 52

Week 0 Week 13 Week 26 Anthropometry X X X

Anthropometry	~	(^)	~	Λ	
Motivation	Х		Х	Х	
Quality of life measure	Х		Х	Х	
Blood pressure	Х	(X)	Х	Х	
Venepuncture	Х		Х		
Psychological function	Х		Х	Х	
Accelerometry	Х		Х		

- 2. Health-related quality of life (HR-QOL): Impact of Weight on Quality of Life-Kids,¹¹ a 27-item instrument consisting of four scales: physical comfort, body esteem, social life and family relations.¹¹ Young people and parents completed separate questionnaires.
- 3. Psychological factors:
 - Eating Attitudes Test.¹² Provides a total score and subscales: (1) dieting; (2) bulimia and food preoccupation; (3) oral control
 - ii. Rosenberg Self-Esteem Scale¹³
 - iii. Psychological health: Development and Well-being Assessment (DAWBA) online interview, which generates likely psychiatric diagnosis at the >50% likely level.¹⁴ Data were missing at follow-up in >50% of cases, therefore we were unable to assess the effect of the intervention on DAWBA outcomes.
- 4. Physical activity; Actigraph accelerometer 7-day measurement.
- 5. Cardiometabolic risk factors; clinical examination and venepuncture after an 8-hour fast:
 - i. Fasting insulin (mU/L) and glucose (mmol/L)
 - ii. Fasting lipids (mmol/L): high-density lipoprotein cholesterol, low-density lipoprotein cholesterol and triglycerides
 - iii. Peripheral, seated blood pressure measured using an electronic Dinamap after 20 min rest.
- 6. Health economic outcomes; preference-based HRQOL, resource utilisation and costs to inform a cost-effectiveness analysis (reported elsewhere).

Demographic and clinical data:

- A. Socioeconomic status assessed using the 2010 Index of Multiple Deprivation (IMD) for postcode.¹⁵
- B. Ethnicity, medical history, pubertal status (self-report) and weight management history.

Data collection

Outcome data were collected at the CRF. Where subjects were unable or unwilling to attend, a home assessment was offered using portable instruments (Seca 875 Flat scales for mobile use and Seca Leicester Height Measure) to prioritise primary outcome data collection (BMI). Serious adverse events (SAE) were monitored by the research team and reported to the steering committee.

Power and sample size

Pilot data identified a likely effect size of 1.7 kg/m² reduction in BMI. Lifestyle modification programmes in obese children result in improvements in HR-QOL of 0.3–0.5 SD.^{16 17} We calculated a sample size of 126 subjects would detect a reduction of approximately 1 kg/m² in BMI (equivalent to 0.5 SD) with 80% power at 5% significance. We initially inflated the sample size to account for clustering due to persistent therapist effects,¹ assuming a therapist cluster size of 10 in both arms and an intra class coefficient (ICC) of 0.025, inflating the size to $126^{*}(1 +$ $(10 - 1)^* 0.025) = 155$. To allow for 20% dropout, we initially aimed to recruit 200 subjects. The required sample size was recalculated mid-trial as mean therapist cluster size was less than 4 in the intervention arm and all control participants bar 1 had a different nurse provider. Using conservative cluster sizes of 4.5 for the intervention arm and 2 for the control arm and a within-study dropout rate of 14%, we planned to recruit at least 155 subjects in order to retain 80% power at a 5% significance threshold.

Fidelity and compliance

Compliance was predefined as attendance at the introductory session plus five or more sessions. A qualified clinical psychologist observed each provider deliver session 1 with their first client then rated the remaining sessions from an audio recording. A Fidelity Adherence Scale based on the Motivational Interviewing Supervision and Training Scale¹⁹ assessed fidelity to content delivery and psychological model. Each session was self-rated by the observer from 1 (poor) to 3 (high).

Statistical analysis

Analyses were by intention to treat. For the primary outcome, a linear regression model adjusted for age, sex and baseline BMI compared BMI at 26 weeks between groups. We fitted a random intercept at therapist level to allow for persistent therapist effects. To adjust for biases caused by missing data, our primary analysis used multiple imputation with chained equations to impute missing BMI measurements at 6 or 12 months, assuming data were missing at random. We used an imputation model with 20 imputations containing age, sex, baseline BMI, treatment group and number of attempts to contact the participant. Secondary analyses included only participants with available outcome data at baseline and 6 or 12 months.

To estimate difference in mean outcomes among compliers, we used a complier average causal effect model.²⁰ This inflates intention-to-treat analyses estimates to adjust for non-compliance, avoiding problems caused by patient selection in per-protocol or on-treatment analyses. Secondary outcomes were analysed using similar methodology. Where outcomes were binary or ordinal, we used logistic or ordinal logistic regression models. For highly skewed continuous variables we used robust SEs. All analyses were performed using Stata V.13.0 (StataCorp, College Station TX).

RESULTS

Five hundred and nineteen young people or families contacted the team. Three hundred and fifty-two completed a telephone screening interview. Two hundred and ten were invited to attend a baseline assessment (figure 1). A small number of young people failed to provide accurate contact details after their initial indication of interest. They were therefore not subsequently contacted.

One hundred and seventy-four young people (88%) were randomised into the trial with 87 in each arm. Primary outcome data on BMI at 26 weeks were collected on 145 (83%) participants (figure 2). Mean age at baseline was 15 years. Mean BMI was 32.0; 63% of participants were female (table 2). The two arms were well balanced with respect to all baseline characteristics.

On average, participants attended 10 of the 12 HELP sessions, with 27 young people (31%) attending all 12 sessions and 69 (79%) meeting the criteria for compliance. Seventy-six per cent of observed sessions were rated as good.

The effect of the intervention on BMI at 26 weeks adjusted for baseline age, sex and BMI was -0.11 kg/m^2 (95% CI -0.62to 0.40, p=0.7), indicating the effect of the intervention was non-significant (table 3). Positive changes reflect an increase, negative is a decrease throughout. Twenty-nine 6-month BMI measurements were imputed. Throughout the results from complete case analyses mirror almost exactly those using multiple imputations.

The effect among compliers was -0.14 kg/m^2 (95% CI -0.78 to 0.51, p=0.7) and the distributions of BMI change at 26 weeks in both arms were very similar (figure 3). Among 145 patients

Original article

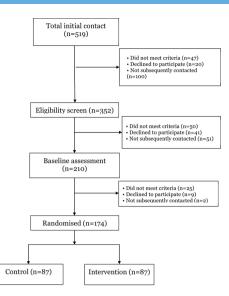


Figure 1 CONSORT (Consolidated Standards of Reporting Trials) Recruitment flow diagram.

with BMI measurements at baseline and 6 months, the measurement at 6 months was lower in 85 (59%) patients. When we compared the number of patients in various categories of change in BMI (>2 kg/m² reduction, $0-2 kg/m^2$ reduction, $0-2 kg/m^2$ increase, $2-4 kg/m^2$ increase, >4 kg/m² increase), there was no evidence of a difference in the distribution of patients among the various categories.

Secondary outcome analyses

There were no significant differences between arms for BMI at 52 weeks (effect -0.22 kg/m^2 , 95% CI -1.05 to 0.61), weight (-0.72 kg, 95% CI -3.28 to 1.84), waist circumference (0.07 cm, 95% CI -1.51 to 1.65) and fat percentage (-0.21%, 95% CI -1.57 to 1.14) (table 3). There were no significant differences for blood pressure, psychological function and measures of lipid

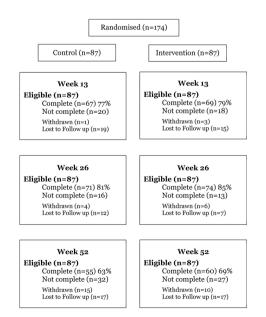


Figure 2 CONSORT (Consolidated Standards of Reporting Trials) flow chart of follow-up of the 174 participants randomised in the Healthy Eating and Lifestyle Programme study.

	Control (n=87)	Intervention (n=87)	
	Median (IQR) or n (%)	Median (IQR) or n (%)	
	15 (14–17)	15 (13–17)	
Age (years)	- ()	. ,	
Female	55 (63%)	54 (62%)	
Ethnicity	24 (44 0/)	(220)	
Black	34 (41%)	18 (22%)	
Asian	13 (16%)	21 (25%)	
White or mixed	36 (43%)	44 (53%)	
Unknown	4 (5%)	4 (5%)	
Anthropometry			
BMI (kg/m ²)	32.0 (29.2–34.6)	32.0 (28.7–35.5)	
BMI z-score	2.8 (2.4–3.3)	2.8 (2.5–3.3)	
Weight (kg)	88.9 (80.0–100.4)	84.4 (76.8–100.9)	
Waist circumference (cm)	99.0 (92.1–107.0)	98.0 (90.6–108.7)	
Estimated fat percentage	44.1 (37.4–47.5)	42.8 (39.0–49.0)	
Psychological scales			
EAT-26			
Eating attitude score (0–39) (n=173)	11 (6–18)	10 (6–17)	
Dieting scale score (0–39) (n=173)	7 (3–11)	6.5 (3–12)	
IWQOL-Kids			
Participant-reported global score (0–100) (n=171)	74 (62–84)	77 (68–87)	
Parent-reported global score (0–100) (n=156)	74 (62–86)	70 (56–81)	
Rosenberg global score (0–30) (n=165)	18 (15–20)	18 (15–23)	
Cardiometabolic risk factors			
Blood glucose (mmol/L) (n=173)	4.4 (4.2–4.6)	4.5 (4.3–4.9)	
Insulin (mmol/L)	11.7 (8.2–18.9)	14.2 (7.8–20.4)	
LDL-C (mmol/L) (n=171)	2.5 (2.1–3.3)	2.7 (2.2–3.1)	
HDL-C (mmol/L) (n=171)	1.1 (1.0–1.3)	1.1 (1.0–1.3)	
Triglycerides (mmol/L) (n=173)	1.0 (0.8–1.2)	1.0 (0.7–1.4)	

All n's are 174 except where stated.

Rosenberg scale—higher score means higher self.

BMI, body mass index; EAT-26, 26-Item Eating Attitudes Test; HDL-C, high-density lipoprotein cholesterol; IWQOL-Kids, Impact of Weight on Quality of Life-Kids; LDL-C, low-density lipoprotein cholesterol.

and glucose metabolism. There were no SAEs reported related to participation in the study.

DISCUSSION

The intervention, previously shown to be promising in clinical practice, did not reduce BMI or improve psychological or cardiometabolic function. Attrition was low compared with other paediatric obesity studies.²¹

We recalculated the estimated dropout rate at the time of recalculation of the sample size. The ICC estimates of 0.025 and a mean cluster size of 10 was a conservative estimate to ensure that we had enough statistical power; at the end of the study, our estimated ICC was <0.01, and our maximum cluster size was 7 suggesting that we had greater than anticipated statistical power.

/ariable	Number with both baseline and outcome data control/intervention	Mean change in control group	Mean change in intervention group	Adjusted difference between intervention and control (95% CI)*	p Value
rimary outcome					
BMI at 26 weeks (kg/m ²)	71/74	0.25	0.18	-0.11 (-0.62 to 0.40)	0.7
econdary outcomes (at 6 weeks unless specified)					
BMI at 52 weeks (kg/m ²)	55/60	0.80	0.50	-0.22 (-1.05 to 0.61)	0.6
BMI z-score	71/74	-0.03	-0.02	0.00 (-0.07 to 0.07)	>0.9
Waist circumference (cm)	61/64	0.16	-0.11	-0.72 (-3.28 to 1.84)	0.6
Weight (kg)	71/74	1.77	2.00	0.07 (-1.51 to 1.65)	0.9
Fat percentage	55/60	1.25	0.71	-0.21 (-1.57 to 1.14)	0.8
Supine systolic BP (mm Hg)	68/73	2.19	3.04	0.01 (-3.24 to 3.26)	>0.9
Supine diastolic BP (mm Hg)	68/73	3.41	2.08	-1.21 (-4.63 to 2.20)	0.5
Eat-26 (0–39)					
Eating attitude score	65/69	-0.72	-0.84	0.15 (-1.24 to 1.54)	0.8
Dieting scale score	65/69	-1.03	-1.26	-0.09 (-2.32 to 2.14)	0.9
IWQOL-Kids (0–100)					
Participant-reported global score	63/69	6.22	5.94	0.14 (-3.53 to 3.81)	0.9
Parent-reported global score	52/50	4.37	7.46	0.51 (-3.91 to 4.93)	0.8
Rosenberg global score	61/64	1.77	1.45	-0.25 (-1.70 to 1.20)	0.7
Insulin (IU/L)	56/61	4.31	3.90	1.51 (-1.46 to 4.48)	0.3
LDL cholesterol (mmol/L)	53/61	-0.20	-0.13	0.09 (-0.07 to 0.26)	0.3
HDL cholesterol (mmol/L)	53/61	-0.08	-0.04	0.02 (-0.06 to 0.09)	0.7
Triglycerides (mmol/L)	55/61	-0.01	-0.07	0.08 (-0.08 to 0.24)	0.3

IWQOL-Kids—Higher score means higher weight-related quality of life.

BMI, body mass index; BP, blood pressure; EAT-26, 26-Item Eating Attitudes Test; HDL, high-density lipoprotein; IWQOL-Kids, Impact of Weight on Quality of Life-Kids; LDL, low-density lipoprotein.

*95% confidence interval.

We were able to exclude clinically important effect sizes for the intervention, such as differences in BMI of 0.6 kg/m^2 at 6 months or 1 kg/m^2 at 12 months.

Fidelity of delivery was good with approximately 80% of participants receiving the intended 'dose' of intervention.

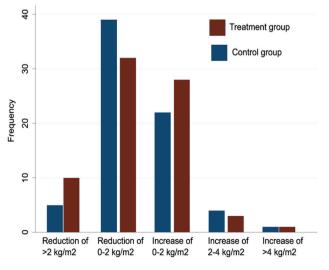


Figure 3 Distribution of changes in body mass index from baseline to 26 weeks in control and treatment groups among 145 participants with measurements at both time points.

Our study was subject to a number of limitations. We widened our eligibility criteria to include adolescents with morbid obesity; however, only 9 participants (4.6%) had baseline BMI between 40 and 45 kg/m^2 . Attrition at 52 weeks reduced the power to identify an effect of the intervention, although it is likely that direction of bias from attrition would have been to preferentially retain those in whom the intervention had been effective and inflate any identified effect. While we had full data on the primary outcome follow-up, we were unable to collect sufficient data on physical activity and psychological morbidity. Given the absence of significant effects on other secondary outcomes, it is unlikely that the intervention would have had an effect on physical activity and psychological morbidity.

Comparison with the literature

Programmes that include adolescents have more variable outcomes than those for earlier childhood.⁴⁵²² Our findings are similar to a number of other published weight management trials of a lower quality. A recent systematic review reported 28 of 31 studies had unclear or high risk of bias due to lack of information/procedures to ensure adequate randomisation/blinding of outcome assessments.²² Recent meta-analyses suggest lifestyle modification programmes in children are associated with a BMI reduction from 1.15 kg/m² ²³ to 1.3 kg/m².⁵ Systematic reviews suggest lifestyle modification interventions improve quality of life²³ and may have small effects on lipids and insulin.⁵ In contrast, we found no impact on BMI, lipids or quality of life.

Original article

There were small non-significant increases in self-esteem. Other studies have shown a benefit in self-esteem measures often in the face of little change in obesity measures.²⁴

Possible explanations for null findings may relate to (A) intervention, (B) methodology or (C) population. It is possible the trial did not provide an adequate test of the intervention; however, it was adequately powered and methodologically robust. Due to slow recruitment, the age range was widened and this, together with other dropouts, may have impacted upon the representativeness of the sample and generalisability of results. It is likely that those who completed were more motivated in both arms, and any bias would be against HELP as that required more input.

A large proportion of control participants achieved a small BMI reduction raising the possibility that the comparator had some effect.

It is possible the population was different from interventions that have identified an effect. Our sample was highly deprived, with approximately 40% in the most deprived IMD quintile (20% expected) and around half from black or minority ethnic groups. Mental health problems were identified in 34% at baseline, despite excluding previously known mental health conditions. This is considerably higher than the general population.²³ Most published studies have been undertaken in hospital or academic settings⁵ in the USA dominated by more affluent white families.⁴ Childhood obesity interventions based on education and personal behavioural change are less likely to be effective in more deprived populations²⁵ as poorer families may face structural and cultural barriers to lifestyle change including financial barriers and fewer family/community resources.

Finally, results may be explained by delivery, content and intensity factors. Our pilot data were obtained from a small clinical programme delivered by highly trained clinical psychologists. Less well-qualified graduates only had 2 days training in behaviour change techniques (and the intervention manual) with regular supervision; however, reduction in therapist skill level may have contributed to our null results.

CONCLUSIONS

HELP was no more efficacious reducing BMI in a community sample of obese adolescents than a single educational session adding to the existing evidence base of lack of effectiveness of weight management trials for children and adolescents. Further work is needed to understand how weight management programmes can be delivered effectively to young people from diverse and deprived backgrounds in which childhood obesity is common. At minimum, this study reinforces the need for higher level, structured interventions to tackle the growing public health burden of obesity in the UK and internationally.

Author affiliations

¹University College London Hospitals and UCL Institute of Epidemiology and Health Care, London, UK

²Great Ormond Street Hospital for Children, London, UK

³Department of Non-communicable Disease Epidemiology, London School of Hygiene and Tropical Medicine, London, UK

⁴University College London School of Pharmacy, London, UK

⁵Primary Care and Population Health, UCL Institute of Epidemiology & Health, London, UK

⁶Population, Policy and Practice Programme, UCL Institute of Child Health, London, UK

⁷Department of Obstetrics and Gynaecology, University of Cambridge, Cambridge, UK

⁸London School of Hygiene and Tropical Medicine, London, UK ⁹UCL Institute of Epidemiology & Health, London, UK Acknowledgements We are grateful for the contributions of our Trial Steering Committee (Independent Members: Professor Carolyn Summerbell (Durham University), Dr Edna Roche (University of Dublin), Dr Mike Robling (Cardiff University), Ms Sandra Wharton (Independent Adviser, Mathematics, Functional Skills and Whole School Improvement)), Data Monitoring Committee (Independent members: Professor John W Gregory (Chair, Wales School of Medicine), Professor Mark Shevlin (Statistician, University of Ulster)) and Ethics Committee (NRES Committee London—Riverside, National Research Ethics Service (NRES), Bristol REC Centre). We would like to thank Saffron Karlsen for her input into the trial design and economic analysis.

Contributors The trial was conceptualised by DC and RMV. The intervention was developed by DC with input from RMV. RMV and DC developed the trial design, with input from SK, ICKW, IN and TJC. TJC and US developed the statistical plan, with input from RMV and JG. ASK, AM and LDH contributed to trial design and writing of the protocol. SM and MP contributed to the trial design and undertook the economic analysis. RH supervised the providers and analysed the fidelity data and process evaluation. All authors read and approved the final manuscript.

Funding This paper presents independent research funded by the NIHR under its Programme Grants for Applied Research programme (Grant Reference Number RP-PG-0608-10035) – the Paediatric Research in Obesity Multi-model Intervention and Service Evaluation (PROMISE) programme). The views expressed are those of the author(s) and not necessarily those of the NIHS, the NIHR or the Department of Health. The HELP research team acknowledges the support of the NIHR, through the Primary Care Research Network. TJC was funded by MRC grant MR/M012069/1.

Competing interests ASK is director of International Public Health at Public Health England (PHE). The views represented in this paper are those of the author and do not necessarily represent those of PHE. All other authors declare no competing interests.

Ethics approval The study was approved by National Research Ethics Service, West London REC 3, on the 27 August 2010. Research Ethics Committee (REC) reference number 10/H0706/54.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Data are available upon request from the investigators RMV and DC.

Open Access This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/

© Article author(s) (or their employer(s) unless otherwise stated in the text of the article) 2017. All rights reserved. No commercial use is permitted unless otherwise expressly granted.

REFERENCES

- Lobstein T, Leach RJ. Tackling obesities: future choices-International comparisons of obesity trends, determinants and responses-Evidence review – 2. children: Foresight, Government Office of the Chief Scientit, 2007.
- 2 Ells LJ, Hancock C, Copley VR, et al. Prevalence of severe childhood obesity in England: 2006-2013. Arch Dis Child 2015;100:631–6.
- 3 Centre for Public Health Excellence at NNational Collaborating Centre for Primary C. National Institute for Health and Clinical Excellence: Guidance. In: Obesity: The Prevention, Identification, Assessment and Management of Overweight and Obesity in Adults and Children. London, UK: National Institute for Health and Clinical Excellence, 2006.
- 4 Oude Luttikhuis H, Baur L, Jansen H, et al. Interventions for treating obesity in children. The Cochrane database of systematic reviews 2009;1:Cd001872.
- 5 Ho M, Garnett SP, Baur L, et al. Effectiveness of lifestyle interventions in child obesity: systematic review with meta-analysis. *Pediatrics* 2012;130:e1647–71.
- 6 Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the New Medical Research Council quidance. BMJ 2008;337:a1655.
- 7 Christie D, Hudson L, Mathiot A, *et al*. Assessing the efficacy of the Healthy Eating and Lifestyle Programme (HELP) compared with enhanced Standard care of the Obese Adolescent in the community: study protocol for a randomized Controlled trial. *Trials* 2011;12:242.
- 8 Christie D, Channon S. The potential for motivational interviewing to improve outcomes in the management of diabetes and obesity in paediatric and adult populations: a clinical review. *Diabetes Obes Metab* 2014;16:381–7.
- 9 George E, Iveson C, Ratner H. Problem to solution: brief therapy with individuals and families: BT Press, 1999.
- Haroun D, Croker H, Viner RM, et al. Validation of BIA in obese children and adolescents and re-evaluation in a longitudinal study. Obesity 2009;17:2245–50.
- Kolotkin RL, Zeller M, Modi AC, et al. Assessing weight-related quality of life in adolescents. Obesity 2006;14:448–57.

- 12 Garner D. *Eating disorder Inventory-2: professional Manual*. Florida: Psychological Assessment Resources. In: Inc, 1991.
- 13 Rosenberg M. Society and the adolescent Self-image. Middletown, CT: Wesleyan University Press, 1989.
- 14 Goodman R, Ford T, Richards H, et al. The Development and Well-Being Assessment: description and initial validation of an integrated assessment of child and adolescent psychopathology. J Child Psychol Psychiatry 2000;41:645–55.
- 15 The English indices of deprivation 2010. London: Department for Communities and Local Government, 2011. https://www.gov.uk/government/statistics/english-indicesof-deprivation-2010
- 16 Wille N, Erhart M, Petersen C, et al. The impact of overweight and obesity on healthrelated quality of life in childhood-results from an intervention study. BMC Public Health 2008;8:421.
- 17 Robertson W, Friede T, Blissett J, et al. Pilot of "Families for Health": community-based family intervention for obesity. Arch Dis Child 2008;93:921–6.
- Lee KJ, Thompson SG. Clustering by health professional in individually randomised trials. BMJ 2005;330:142–4.

- 19 Madson MB, Campbell TC, Barrett DE, et al. Development of the Motivational Interviewing Supervision and training Scale. Psychol Addict Behav 2005;19:303–10.
- 20 Angrist JD, Imbens GW, Rubin DB. Identification of Causal Effects using instrumental variables. J Am Stat Assoc 1996;91:444–55.
- 21 Skelton JA, Beech BM. Attrition in paediatric weight management: a review of the literature and new directions. *Obes Rev* 2011;12:e273–81.
- 22 Peirson L, Fitzpatrick-Lewis D, Morrison K, et al. Treatment of overweight and obesity in children and youth: a systematic review and meta-analysis. CMAJ Open 2015;3:E35–46.
- 23 Meltzer H, Gatward R, Goodman R, et al. Mental health of children and adolescents in Great Britain. Int Rev Psychiatry 2003;15:185–7.
- 24 French SA, Story M, Perry CL. Self-esteem and obesity in children and adolescents: a literature review. *Obes Res* 1995;3:479–90.
- 25 Beauchamp A, Backholer K, Magliano D, et al. The effect of obesity prevention interventions according to socioeconomic position: a systematic review. Obes Rev 2014;15:541–54.



A community-based motivational personalised lifestyle intervention to reduce BMI in obese adolescents: results from the Healthy Eating and Lifestyle Programme (HELP) randomised controlled trial

Deborah Christie, Lee Duncan Hudson, Sanjay Kinra, Ian Chi Kei Wong, Irwin Nazareth, Tim J Cole, Ulla Sovio, John Gregson, Anthony S Kessel, Anne Mathiot, Stephen Morris, Monica Panca, Silvia Costa, Rebecca Holt and Russell M Viner

Arch Dis Child 2017 102: 695-701 originally published online July 7, 2017 doi: 10.1136/archdischild-2016-311586

Updated information and services can be found at: http://adc.bmj.com/content/102/8/695

	These include:
References	This article cites 19 articles, 5 of which you can access for free at: http://adc.bmj.com/content/102/8/695#BIBL
Open Access	This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/
Email alerting service	Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.
Topic Collections	Articles on similar topics can be found in the following collections Editor's choice (150) Open access (224)
Notes	

To request permissions go to: http://group.bmj.com/group/rights-licensing/permissions

To order reprints go to: http://journals.bmj.com/cgi/reprintform

To subscribe to BMJ go to: http://group.bmj.com/subscribe/